### III.    Claims

This version and listing of the claims replaces all prior versions and listings of the claims.

1.    (currently amended) A computer implemented method of processing an electrocardiogram (ECG), comprising the steps of:

receiving digital parameter data for a clinical study, said digital parameter data representing demographic data to be collected for ECGs associated with said clinical study and rules associated with said clinical study; ~~and~~

traversing collected demographic data against said digital parameter data to identify problems with said collected demographic data; and

automatically generating a query when a problem is identified with said collected demographic data based upon said traversing step ~~digital parameter data~~, said query eliciting resolution of said problem.

2.    (previously presented) The method of claim 1,

wherein said problem is identified as requiring either internal query resolution or external query resolution,

wherein said digital parameter data include query resolution contact information identifying a source of query resolution,

said automatically generating step further comprising the step of generating a query for an external contact in accordance with said query resolution contact information if said problem is identified as requiring external query resolution.

3.    (previously presented) The method of claim 2, further comprising notifying an internal contact of said problem if said problem is identified as requiring internal query resolution.

4.      (original) The method of claim 2, wherein said query resolution contact information includes an identification of a party to be contacted and a contact method.

5.      (currently amended) The method of claim 1, wherein said ~~traversing~~ step ~~of automatically generating said query~~ includes the step of identifying whether demographic data are missing from said collected demographic data, said collected demographic data violate a rule associated with said clinical study, or said collected demographic data are inconsistent with demographic data received for a second ECG associated with said clinical study, or a combination thereof.

6.      (previously presented) A computer implemented method of processing an electrocardiogram (ECG), comprising the steps of:

    receiving digital ECG data for a plurality of ECGs for a plurality of patients within a clinical study, said digital ECG data evincing a plurality of heartbeats detected during said plurality of ECGs for each patient from said plurality of patients;

    after said ECG data is received, measuring at least one interval for each of said plurality of ECGs;

    providing said ECGs to at least one evaluating physician and respective interval duration measurement data on a display for medical evaluation;

    receiving digital evaluation data representing a medical evaluation by said at least one evaluating physician of respective ECGs from said plurality of ECGs; and

    automatically flagging at least one ECG from said plurality of ECGs for re-measurement of said at least one interval and/or re-evaluation by an evaluating physician based on quality review rules.

7.      (previously presented) The method of claim 6, further comprising displaying respective annotated ECG images to said evaluating physician for ECGs to be evaluated by said

evaluating physician, said annotated ECG images showing markings identifying said at least one interval.

8.      (previously presented) The method of claim 6, further comprising the steps of:

receiving digital parameter data for said clinical study, said digital parameter data representing said quality review rules,

said automatically flagging step including the step of identifying said at least one ECG based at least in part on said digital evaluation data and/or said interval duration measurement data.

9.      (canceled)

10.     (previously presented) A computer implemented method of processing an electrocardiogram (ECG), comprising the steps of:

receiving digital ECG data for a plurality of ECGs for a plurality of patients within a clinical study, said digital ECG data evincing a plurality of heartbeats detected during said ECGs;

receiving digital interval duration data, said digital interval duration data representing time durations of measured intervals associated with heartbeats from said plurality of heartbeats; and

providing said digital ECG data and digital interval duration data to a regulatory agency processor through a computer network from a computer processor unit remote from said regulatory agency processor.

11.     (currently amended) An electrocardiogram (ECG) processing system, comprising:

means for receiving digital parameter data for a clinical study, said digital
parameter data representing demographic data to be collected for ECGs associated with said
clinical study and rules associated with said clinical study; ~~and~~

~~means for traversing collected demographic data against the digital parameter data~~
~~to identify problems with said collected demographic data; and~~

means for automatically generating a query when a problem is identified with ~~the~~
collected demographic data based upon said <u>traversing step</u> ~~digital parameter data~~, said query
eliciting resolution of said problem.

12.     (previously presented) The system of claim 11,

wherein said problem is identified as requiring either internal query resolution or
external query resolution,

wherein said digital parameter data include query resolution contact information
identifying a source of query resolution,

said automatically generating means further comprises means for generating a
query for an external contact in accordance with said query resolution contact information if said
problem is identified as requiring external query resolution.

13.     (previously presented) The system of claim 12, further comprising means for
notifying an internal contact of said problem if said problem is identified as requiring internal
query resolution.

14.     (original) The system of claim 12, wherein said query resolution contact
information includes an identification of a party to be contacted and a contact method.

15.     (currently amended) The system of claim 11, wherein said ~~automatically~~
~~generating said query~~ <u>traversing</u> means includes means for identifying whether demographic data

are missing from said collected demographic data, said collected demographic data violate a rule associated with said clinical study, or said collected demographic data are inconsistent with demographic data received for a second ECG associated with said clinical study, or a combination thereof.

16.     (previously presented) An electrocardiogram (ECG) processing system, comprising:

means for receiving digital ECG data for a plurality of ECGs for a plurality of patients within a clinical study taken with at least one remote electrocardiogram machine, said digital ECG data evincing a plurality of heartbeats detected during said plurality of ECGs for each patient from said plurality of patients;

means for, after said ECG data is received, measuring at least one interval for each of said plurality of ECGs;

means for providing said ECGs to at least one evaluating physician and respective interval duration measurement data on a display for medical evaluation;

means for receiving digital evaluation data representing a medical evaluation by said at least one evaluating physician of respective ECGs from said plurality of ECGs; and

means for automatically flagging at least one ECG from said plurality of ECGs for re-measurement of said at least one interval and/or re-evaluation by an evaluating physician based on quality review rules.

17.     (previously presented) The system of claim 16, further comprising means for displaying on a monitor respective annotated ECG images to said evaluating physician for ECGs to be evaluated by said evaluating physician, said annotated ECG images showing markings identifying said at least one interval.

18.     (previously presented) The system of claim 16, further comprising:

means for receiving digital parameter data for said clinical study, said digital parameter data representing said quality review rules,

said automatically flagging means including means for identifying said at least one ECG based at least in part on said digital evaluation data and/or said interval measurement duration data.

19.     (canceled)

20.     (canceled)

21      (currently amended) A method of processing an electrocardiogram (ECG), comprising the steps of:

(a)     receiving digital ECG data for an ECG lead, said digital ECG data evincing a plurality of a patient's heartbeats detected during an ECG;

(b)     displaying an ECG tracing image of said plurality of heartbeats on a display of a user terminal;

(c)     after step (b), receiving from a user an identification of interval points for at least one interval on said displayed ECG tracing image to be measured;

(d)     determining a time duration of said at least one interval based at least in part on said identified interval points; ~~and~~

(e)     recording digital annotation data representing said identified interval points for said at least one interval <u>apart from said ECG tracing image;</u> [[,]]

(f)     <u>retrieving said recorded digital annotation data;</u>

(g)    combining said retrieved recorded digital annotation data with said digital
ECG data to develop an annotated ECG tracing image showing markings corresponding to said
identified interval points; and

(h)    displaying said annotated ECG tracing image on a display.

~~wherein an annotated ECG tracing image showing markings corresponding to said~~
~~identified interval points is developable from said digital ECG data and said digital annotation~~
~~data.~~

22.    (previously presented) The method of claim 21, wherein said step (c) comprises:

displaying at least one movable caliper on said display over said ECG tracing
image;

receiving through an input device a selection of said interval points on said ECG
tracing image with said movable caliper; and

recording data corresponding to said selection.

23.    (previously presented) The method of claim 22, wherein said displayed ECG
tracing image includes at least 3 heartbeats, wherein step (c) comprises receiving an
identification of interval points for at least 3 intervals associated with said at least 3 heartbeats
from said ECG tracing image.

24.    (previously presented) The method of claim 23, wherein said intervals are
selected from the group consisting of PR, QT, RR and QRS intervals or a combination thereof.

25.    (previously presented) The method of claim 22, further comprising recording said
time duration as digital interval duration measurement data.

26.     (previously presented) The method of claim 21, wherein an identification of interval points for a plurality of intervals on said ECG tracing image to be measured are received.

27.     (previously presented) The method of claim 21, wherein said at least one interval is a PR, QT, RR or QRS interval.

28.     (previously presented) The method of claim 21, wherein digital ECG data are received for a plurality of ECG leads, said method further comprising the step of receiving a selection of at least one ECG lead for use in step (c).

29.     (currently amended) The method of claim 21, further comprising the steps of:

~~retrieving said digital annotation data;~~

~~developing said annotated ECG tracing image showing said markings from said digital ECG data and said retrieved digital annotation data;~~

wherein said ~~displaying said~~ annotated ECG tracing image ~~includes on a~~ is displayed to an evaluating physician, the method further comprising the step of:~~; and~~

receiving a medical evaluation of said annotated ECG tracing image by said evaluating physician.

30.     (previously presented) The method of claim 29, further comprising retrieving digital interval duration data associated with said determined time duration, and providing said time duration to said evaluating physician.

31.     (currently amended) The method of claim 30 further comprising the steps of:

automatically generating a report for said annotated ECG image, said report including said medical evaluation; and

automatically providing said report to a party identified by digital reporting criteria for ~~said~~ <u>a</u> clinical study and in a manner identified by said digital reporting criteria.

32.      (previously presented) A system for processing an electrocardiogram (ECG), comprising:

(a)      means for receiving digital ECG data for an ECG lead, said digital ECG data evincing a plurality of a patient's heartbeats detected during an ECG;

(b)      means for displaying an ECG tracing image of said plurality of heartbeats on a display of a user terminal;

(c)      means for receiving from a user an identification of interval points for at least one interval to be measured on said displayed ECG tracing image;

(d)      means for determining a time duration of said at least one interval based at least in part on said identified interval points; and

(e)      means for recording digital annotation data representing said identified interval points for said at least one interval[[,]] <u>apart from said ECG tracing image;</u>

<u>(f)      means for retrieving said recorded digital annotation data;</u>

<u>(g)      means for combining said retrieved recorded digital annotation data with said digital ECG data to develop an annotated ECG tracing image showing markings corresponding to said identified interval points; and</u>

<u>(h)      means for displaying said annotated ECG tracing image on a display.</u>

~~wherein an annotated ECG tracing image showing markings corresponding to said identified interval points is developable from said digital ECG data and said digital annotation data.~~

33.    (previously presented) The system of claim 32, wherein means (c) comprises:

means for displaying at least one movable caliper on said display over said ECG tracing image;

means for receiving through an input device a selection of said interval points on said ECG tracing image with said movable caliper; and

means for recording data corresponding to said selection.

34.    (previously presented) The system of claim 33, wherein said displayed ECG tracing image includes at least 3 heartbeats, wherein means (c) comprises means for receiving an identification of interval points for at least 3 intervals associated with said at least 3 heartbeats from said ECG tracing image.

35.    (previously presented) The system of claim 34, wherein said intervals are selected from the group consisting of PR, QT, RR and QRS intervals or a combination thereof.

36.    (previously presented) The system of claim 33, further comprising means for recording said time duration as digital interval duration measurement data.

37.    (previously presented) The system of claim 32, wherein said receiving means comprises means for receiving an identification of interval points for a plurality of intervals on said ECG tracing image to be measured.

38.    (previously presented) The system of claim 32, wherein said at least one interval is a PR, QT, RR or QRS interval.

39.    (previously presented) The system of claim 32, wherein digital ECG data are received for a plurality of ECG leads, said system further comprising means for receiving a selection of at least one ECG lead for use by means (c).

40.    (currently amended) The system of claim 32, further comprising:

~~means for retrieving said digital annotation data;~~

~~means for developing said annotated ECG tracing image showing said markings from said digital ECG data and said retrieved digital annotation data;~~

<u>wherein said</u> means for displaying said annotated ECG tracing image <u>displays said annotated ECG tracing image</u> ~~on a display~~ to an evaluating physician<u>, the system further comprising</u> ~~; and~~

—means for receiving a medical evaluation of said annotated ECG tracing image by said evaluating physician.

41.     (previously presented) The system of claim 40, further comprising means for retrieving digital interval duration data associated with said determined time duration, and providing said time duration to said evaluating physician.

42.     (currently amended) The system of claim 41,

means for automatically generating a report for said annotated ECG image, said report including said medical evaluation; and

means for automatically providing said report to a party identified by digital reporting criteria for ~~said~~ <u>a</u> clinical study and in a manner identified by said digital reporting criteria.

43.     (previously presented) The method of claim 1, further comprising the steps of:

receiving collected demographic data respective to a plurality of ECGs to be medically evaluated and associated with said clinical study;

before an individual ECG from said plurality of ECGs is made available for medical evaluation, comparing said collected demographic data associated with said individual ECG against said received digital parameter data; and

if a query is generated associated with said individual ECG, flagging said individual ECG as unavailable for medical evaluation until said query is resolved.

44.    (previously presented) The system of claim 11, further comprising:

means for receiving collected demographic data respective to a plurality of ECGs to be medically evaluated and associated with said clinical study; ·

means for, before an individual ECG from said plurality of ECGs is made available for medical evaluation, comparing said collected demographic data associated with said individual ECG against said received digital parameter data; and

means for, if a query is generated associated with said individual ECG, flagging said individual ECG as unavailable for medical evaluation until said query is resolved.

45.    (previously presented) The method of claim 6, further comprising providing said at least one ECG for re-measurement or re-evaluation if said at least one ECG is flagged.

46.    (previously presented) The system of claim 16, further comprising means for providing said at least one ECG for re-measurement or re-evaluation if said at least one ECG is flagged.

47.    (previously presented) The method of claim 21, wherein step (c) comprises receiving an identification of interval points for a plurality of intervals, said plurality of intervals being associated with at least two displayed heartbeats from said plurality of heartbeats.

48.    (previously presented) The method of claim 47, wherein said intervals are selected from the group consisting of PR, QT, RR, and QRS intervals.

49.    (previously presented) The method of claim 47, further comprising receiving an identification of interval points for a plurality of intervals for each of said at least two heartbeats.

50.    (previously presented)  The method of claim 21, further comprising the steps of:

after step (e), retrieving said recorded digital annotation data;

developing said annotated ECG tracing image showing said markings from said digital ECG data and said retrieved recorded digital annotation data; and

displaying said annotated ECG tracing image on a display.

51.    (previously presented) The system of Claim 32, wherein means (c) comprises means for receiving an identification of interval points for a plurality of intervals, said plurality of intervals being associated with at least two displayed heartbeats from said plurality of heartbeats.

52.    (previously presented) The system of Claim 51, wherein said intervals are selected from the group consisting of PR, QT, RR, and QRS intervals.

53.    (previously presented) The system of Claim 51, wherein means (c) further comprises means for receiving an identification of interval points for a plurality of intervals for each of said at least two heartbeats.

54.    (previously presented) The system of claim 32, further comprising:

means for retrieving said recorded digital annotation data;

means for developing said annotated ECG tracing image showing said markings from said digital ECG data and said retrieved recorded digital annotation data; and

means for displaying said annotated ECG tracing image on a display.